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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,123	04/05/2001	Yoshiharu Doi	07898-070001	9955

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Fish & Richardson
4350 La Jolla Village Drive Suite 500
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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

12

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,123

Applicant(s)

DOI ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☒ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>g</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicants amendment of the specification, and claims 1-8, and 10-12 and the addition of new claims 13-15, Paper No. 11, 5/28/2003, is acknowledged. Claims 1-15 are at issue and are present for examination. Applicants' arguments filed on 5/28/2003, Paper No. 11, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claims 2, 4 and 6 are objected to because of the following informalities:

Claims 2, 4 and 6 are objected to for applicants newly added recitation "wherein the number of deleted, substituted, or added amino acids is between 2 and 5 or between 5 and 10". It is suggested that if it is the intent of applicants that the specified sequences may altered by deletion, substitution, or addition of between 2 and 5 or between 5 and 10 amino acids that this be amended to "wherein the number of deleted, substituted, or added amino acids is between 2 and 10".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4 and 6 are indefinite in that the newly amended recitation (using claim 2 as an example) “(b) a protein having an amino acid sequence including deletion, substitution, or addition of **one or more amino acids** relative to the amino acid sequence represented by SEQ ID NO: 2 or 4, and having polyester polymerase activity, wherein the number of deleted, substituted, or added amino acids is between **2 and 5 or between 5 and 10**” is unclear. Specifically is it applicants intent that the referred to sequence be modified by deletion, substitution, or addition of one or more amino acids or between 2 and 5 or between 5 and 10 amino acids. Applicants attention is directed to the fact that **one** is not between **2 and 5** or between **5 and 10** amino acids. Claims 4 and 6 are similarly indefinite as illustrated for claim 2 above.

Claims 13, 14 and 15 are indefinite in the recitation of “stringent conditions” as the specification does not define what conditions constitute “stringent”. While each of the claims recite some conditions which are “included”, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a DNA containing SEQ ID NOs:1, 3, 5, or 7, a sequence must be to be included within the scope of these claims.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **1-15** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The original rejection is stated in the previous office action as it applied to previous claims **1, 2, 4, 6, 8 and 10-12**. In response to this rejection applicants have amended the claims and traverse the rejection as it applies to the newly amended claims.

Applicants submit that the Office is trying to limit the claimed invention to specific examples in view of a broader disclosure and the office has the burden of proof to show why one of skill in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Applicants further submit that relevant host cells are described in the specification as filed and such hosts do not include "any host", but rather "any host that has a polyhydroxybutanoic acid polymerase gene". Applicants also submit that one of skill in the art can easily identify polyester polymerase genes, beta-ketothiolase genes and NADPH-acetoacetyl CoA reductase genes, genes that are applicable to the claimed invention.

Applicants argument is not found persuasive. Applicants claims **1, 2, 4, 6, 8 and 10-12** continue to be directed to all possible transformants comprising any host, wherein

a polyhydroxybutanoic acid polymerase gene in the host cell is disrupted with a recombinant vector containing any DNA selected from any polyester polymerase gene, any β -ketothiolase gene and any NADPH-acetoacetyl CoA reductase gene (claim 1), wherein **one of the choices** of genes on the recombinant vector comprise a variant of a specific amino acid sequence (claims 2, 4 and 6), wherein said transformant is a bacterium belonging to the genus *Pseudomonas* or the genus *Ralstonia* (claim 8) and methods of producing a copolymer comprising culturing said transformants (claims 10-12).

Applicants argument is not found persuasive because given all disclosed distinguishing identifying characteristics, in view of the level of skill and knowledge in the art, one would not recognize from the disclosure that applicant was in possession of the claimed invention. Specifically applicants were not in possession of all possible polyhydroxybutanoic acid polymerase genes nor all possible host cells comprising such a polyhydroxybutanoic acid polymerase gene. Further applicants description does not put them in possession of all possible polyester polymerase genes, all possible β -ketothiolase gene and all possible NADPH-acetoacetyl CoA reductase genes. The specification provides a single representative species of transformant, *Pseudomonas* sp. strain 61-3 (JCM10015) transformed with a recombinant vector comprising the DNA sequences of SEQ ID NOs : 1 or 3, 5, and 7, encompassed by these claims. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and

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exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

It is noted that prior to applicants previous amendment, the claims were directed to a transformant in which the polyhydroxybutanoic acid polymerase gene in the host cell is disrupted with a recombinant vector **containing** a polyester polymerase gene, a β -ketothiolase gene **and** a NADPH-acetoacetyl CoA reductase gene. Now applicants have amended the invention such that the claims are directed to a transformant in which the polyhydroxybutanoic acid polymerase gene in the host cell is disrupted with a recombinant vector containing any DNA **selected from** any polyester polymerase gene, any β -ketothiolase gene and any NADPH-acetoacetyl CoA reductase gene. Thus applicants have in response to the previous office action considerably broadened the scope of the claimed transformants. As claims 2-15 merely limit one of the many limitations of the claimed genus, they do not limit the claimed invention such that they are sufficiently described. With respect to these claims as with respect to claims 2, 4 and 6 applicants intention is drawn to the fact that these claims merely limit the choices of possible genes used for disruption or the possible choice of host cell, without narrowing the other possible options of the claimed transformant.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Further, amended claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention because the newly added limitation wherein "the recombinant vector contains **any DNA selected from** any polyester polymerase gene, any β -ketothiolase gene and any NADPH-acetoacetyl CoA reductase gene" is not supported by the original specification and thus the invention that results from this amendment is considered new matter. Applicants have support for a disruption by a recombinant vector which contains a polyester polymerase gene, a β -ketothiolase gene **and** a NADPH-acetoacetyl CoA reductase gene, but not for a recombinant vector which contains **merely one** of the referred to genes.

The rejection of claims 9 and 10-12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is hereby withdrawn given applicants deposit of *Pseudomonas* sp. Strain 61-3, under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure.

Claim Rejections - 35 USC § 102

The rejection of claims 1-8 and 10-12 under 35 U.S.C. 102(a) as being anticipated by Matsusaki et al. (Applied Microbiology and Biotechnology, Vol. 53, pages

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401-409, 2000, See IDS) is hereby withdrawn based on the submission of an English translation of applicants priority document JAPAN 225102/1999.


Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

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August 1, 2003